Submission for medicine reclassification for consideration by the Medicines Classification Committee

This form should be completed in conjunction with the directions in the guidance document 'How to change the legal classification of a medicine in New Zealand.'

Please also complete an introduction summarising the intention of the submission and provide any relevant background.

Once completed, this application should be sent to the MCC Secretariat (committees@health.govt.nz) by the deadline on the dates and deadlines page on the Medsafe website.

By submitting this form, you are confirming that all information is true and accurate, and understanding that this information and any appendices and/ or supporting information that is not considered commercially confidential under the Official Information Act 1982 will be published on the Medsafe website.

Introduction

Please provide background context for the submission

GSK New Zealand is providing evidence to support the reclassification of AREXVY for adults aged 50 to 59 years of age (YOA) at increased risk (AIR) of respiratory syncytial virus (RSV) disease for pharmacist and authorised vaccinators to be reviewed by the Medicines Classification Committee at its 74th meeting.

AREXVY is now approved for adults aged 50-59 years of age at increased risk of RSV disease.

The recent label expansion of AREXVY to include adults aged 50 to 59 years at increased risk of RSV disease (Medsafe, 2025) means that more patients can now be protected against RSV-associated disease ahead of the 2025 RSV season. This is in line with other international approvals, including those in the US, EU, and Australia.

MCC has already recommended the reclassification of AREXVY for adults 60 years of age or older on the 18th of December 2024 to enable access for patients ahead of the 2025 winter season. To date, from January to April 2025, 154 doses of AREXVY have been administered via pharmacies.

GSK now seeks to align the classification with the Medsafe approved indication to include people aged 50 to 59 years of age who are at increased risk of RSV disease. This ensures the same level of access in this patient population as those 60 years and older already covered under the classification.

Burden of RSV disease of in adults 50 to 59 years of age at increased risk

Adults aged 50 and older with underlying medical conditions are at increased risk for hospitalisation following RSV infection compared to those without such conditions (Branche, et al., 2021). While the population-based rates of RSV disease among adults aged 50 to 59 are lower than in older adults (Havers, et al., 2024), individuals in this age group with co-morbidities are still at elevated risk for RSV hospitalisations (Britton, et al., 2025).

Co-morbidities that increase the risk of RSV-associated hospitalisation include chronic kidney disease, chronic obstructive pulmonary disease (COPD), severe obesity, asthma, and coronary artery disease (Woodruff, 2024).

A study on the NZ-based population found that adults aged 50 to 80 with chronic medical conditions face a significantly higher risk of RSV hospitalisation. Those with COPD had hospitalisation rates ten times higher, and those with asthma had rates seven to eight times higher than individuals without these conditions. The highest risks were seen in adults with COPD, congestive heart failure (CHF) or asthma. Additionally, Māori, and Pacific individuals were more likely to have chronic medical conditions compared to those of European or other ethnicities ($P < .001$) (Prasad, et al., 2020)

A recent study in New Zealand demonstrated that RSV hospitalisations predominantly affected young infants, the elderly, indigenous ethnic groups, and those in deprived areas. These patterns remained consistent post-COVID, with increased cases in older children and younger adults. Māori, Pacific ethnicities, and socioeconomically deprived households were disproportionately impacted. Access to pharmacy vaccination may help mitigate these health inequities (Turner, et al., 2024).In the GSK study assessing the immunogenicity and safety of the AREXVY vaccine in adults 50 to 59 years AIR, the predefined co-morbid medical conditions that increase the risk of RSV disease are chronic pulmonary disease, chronic cardiovascular disease, diabetes mellitus types 1 and 2, chronic renal disease, and

chronic liver disease (Ferguson et al., 2024). This is a population of patients that commonly presents to pharmacies for annual recommended vaccinations, including influenza and COVID vaccinations. The findings of this study indicated that a single dose of the AREXVY vaccine elicited an immunological response in individuals aged 50 to 59 that was not inferior to the response observed in those aged 60 and above, for whom the vaccine's efficacy had already been established. Additionally, the safety profile for the 50 to 59 age group was comparable to that of the ≥60 age group (Ferguson, et al., 2024).

On 16 April, the US Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) voted in favour of recommending the use of RSV vaccines in adults 50 to 59 years of age (YOA) who are at increased risk for severe RSV disease (GSK, 2025). This definition of increased risk includes people with COPD, asthma, diabetes, heart disease, and those in residential care (Centers for Disease Control and Prevention (CDC, 2024).

Pharmacists are already well-trained to vaccinate adult patients

Vaccinators are well-prepared for AREXVY administration since the launch of AREXVY vaccine in May 2024, and GSK provides ongoing education and support for successful vaccination implementation in collaboration with Immunisation Advisory Centre (IMAC).

Pharmacists are increasingly crucial in community immunisation, enhancing access to essential vaccines (Te Whatu Ora, 2024)

To date 11 million doses up to March 2025 have been administered in the US alone to help protect millions of adults against RSV associated lower respiratory disease. (Gerber, 2025) and GSK New Zealand estimate around 2,400 adults over 60 years of age and older in New Zealand have received AREXVY since launch in May 2024. As of 2025, GSK New Zealand estimates around 22% of AREXVY has been administered through Pharmacy. This underscores the importance of the role that pharmacists play in ensuring that patients at risk of RSV disease are promptly protected.

In 2024, pharmacies delivered nearly 500,000 influenza vaccine doses, a record number nearly matching general practice. (Hopkinson, 2024)

These developments highlight the expanding role of pharmacists in New Zealand's immunisation strategy, supported by regulatory changes. By offering a broader range of vaccines, pharmacists are instrumental in improving public health outcomes and ensuring wider community protection against vaccine preventable diseases.

Part A- Regulatory Context and Proposed Classification

1. International non-proprietary (INN) name of the medicine

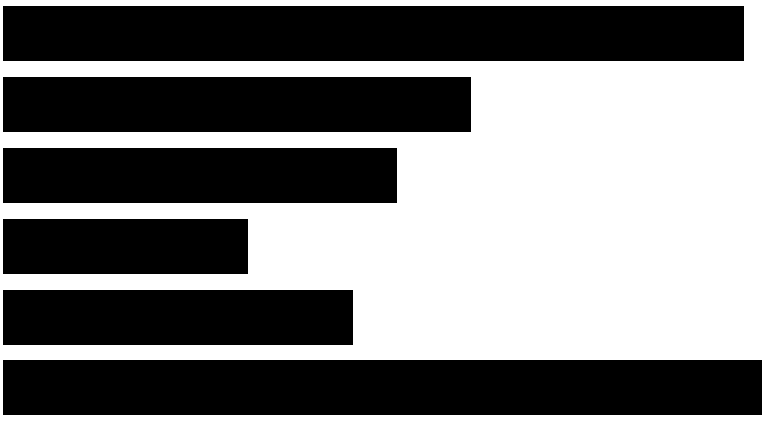
- Respiratory Syncytial Virus vaccine, adjuvanted

2. Proprietary names (if applicable)

- AREXVY 120 micrograms powder and suspension for suspension for injection

3. Name and contact details of the company/ organisation/ individual requesting a reclassification

Contact details can be removed from the form prior to publication of the Medsafe website if requested.



4. Dose form(s) and strength(s) for which a change is sort (if applicable)

- AREXVY is administered as a single dose of 0.5 mL.

5. Pack size, storage conditions and other qualifications (if applicable)

AREXVY is available in a pack size of 1 vial of powder plus 1 vial of suspension.

- Powder for 1 dose in a vial (type I glass) with stopper (butyl rubber).
- Suspension for 1 dose in a vial (type I glass) with a stopper (butyl rubber).
- *Not all pack sizes and container types may be distributed in New Zealand.*
- Store in a refrigerator (2 °C – 8 °C).
  Do not freeze. Discard if the vial has been frozen.
  Store in the original package to protect from light.
  After reconstitution, the vaccine should be used promptly; if not possible, the vaccine should be stored in the refrigerator (2°C – 8°C) or at room temperature up to 25°C. If not used within 4 hours, it should be discarded.

6. Indications for which change is sought (if applicable)

AREXVY has recently received Medsafe approval for an extension of indication which is sought for inclusion in the classification.

Previously the indication was as follows:

> *AREXVY is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older.*
>
> *Consideration should be given to official vaccine recommendations on the appropriate use.*

The approved indication has now been expanded to include adults 50 through 59 years of age who are at increased risk for RSV disease and is as follows:

> *AREXVY is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus RSV-A and RSV-B subtypes in:*
> - *adults 60 years of age and older.*
> - *adults 50 through 59 years of age who are at increased risk for RSV disease.*
>
> *Consideration should be given to official vaccine recommendations on the appropriate use.*

7. Present classification of the medicine

*Prescription **except** when administered for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes to a person 60 years of age or older by registered pharmacists, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by Te Whatu Ora) and who complies with the immunisation standards of Health NZ/Te Whatu Ora.*

8. Classification sought

*Prescription **except** when administered for the prevention of lower respiratory tract disease caused by respiratory syncytial virus RSV-A and RSV-B subtypes to a person 60 years of age and older, or persons 50 through 59 years of age who are at increased risk for RSV disease, by registered pharmacists and/or authorised vaccinator, who have successfully completed the Vaccinator Foundation Course (or any equivalent training course approved by Te Whatu Ora) and who complies with the immunisation standards of Health NZ/Te Whatu Ora.*

9. Classification status in other countries (especially Australia, UK, USA, and Canada), and any justification for harmonisation

AREXVY has been classified to allow administration primarily through pharmacies in the US and the UK. In Canada, pharmacies in most provinces can administer AREXVY. In Australia, AREXVY administration can be initiated without a prescription in all states for adults 50-59 years of age at increased risk and adults 60 years of age and older.

10. Extent of usage in New Zealand and elsewhere (e.g. sales volume) and dates of the original consent to distribute

AREXVY has received approval in 61 countries, including Europe, Japan, and the US for preventing RSV lower respiratory tract disease (LRTD) in individuals aged 60 and older. Additionally, it is approved in the US, EU, Japan, Australia, and New Zealand for use in people aged 50 to 59 at increased risk of RSV (GSK, 2025).

To date 11 million doses up to March 2025 have been administered in the US alone to help protect millions of adults against RSV associated lower respiratory disease.

(Gerber, 2025) and we estimate around 2,400 adults over 60 years of age and older in New Zealand have received AREXVY since launch in May 2024.

The timeline of regulatory authorisations for AREXVY in New Zealand:

- AREXVY gazetted for initial consent to supply in 4 April 2024.
- Reclassification gazetted for administration by pharmacist vaccinator for all individuals 60 years of age and older in December 2024.
- Gazetted for label expansion for adults 50 through 59 years of age who are at increased risk of RSV disease 8 May 2025.

11. Local data or special considerations relating to New Zealand (if applicable)

Local data

Local data indicates that underlying chronic medical conditions significantly elevate the likelihood of RSV hospitalisation in a New Zealand-based population. Adults aged 50 to 80 years of age with COPD had hospitalisation rates ten times higher, and those with asthma had rates seven to eight times higher than individuals without these conditions. The highest relative risks were observed in adults with COPD, CHF, or asthma. Māori and Pacific populations were more likely to have chronic medical conditions compared to European or other ethnicities ($P < .001$) (Prasad, et al., 2020)

A subsequent study showed that RSV hospitalisation patterns remained consistent pre- and post-COVID, with the highest impact on young infants, the elderly, indigenous ethnic groups, and those in deprived areas. Despite the pandemic, these patterns persisted, with increased cases in older children and younger adults. Māori, Pacific populations, and socioeconomically deprived households continued to experience disproportionately higher RSV hospitalisation rates. Improving access to pharmacy vaccination could help address these health inequities. (Turner, et al., 2024)

Co-administration with influenza vaccines

The recent Medsafe regulatory approval has included an expansion to the at risk 50 to 59 years of age population as well as other clinically significant updates to co-administration with other pharmacy delivered vaccines. This recently filing also included data on co-administration of AREXVY with high dose and adjuvanted seasonal influenza vaccines. This data was in addition to co-administration with inactivated standard dose influenza vaccines which was previously approved in AREXVY's initial consent to supply.

In addition, the IMAC recommends AREXVY can be administered concurrently with a number of other vaccines, including those on the National Immunisation Schedule, such as the influenza, COVID-19, and SHINGRIX vaccines. (IMAC, 2025). These vaccines are commonly administered at pharmacies and therefore the broadening of access to enable AREXVY to be administered to patients ages 50 to 59 at increased risk of RSV disease will ensure expedited and easier access for patients as part of routine winter readiness healthcare visits at their local pharmacies.

Remove access barriers to GP clinics

Obtaining vaccinations through GP clinics poses several challenges, including long wait times for appointments, difficulties in registering with a practice and the costs associated with prescriptions. A recent publication in the New Zealand Journal of Medicine highlighted that since 2019, 79% of surveyed general practices have limited or closed enrolments, selectively choosing their patients (HUBNEWS, 2024). This practice can lead to inequitable access to healthcare services and exacerbate existing barriers. Offering vaccinations through community pharmacies and authorised vaccinators is a vital approach to alleviate the pressure on GP clinics and ensure that those most in need can access vaccinations.

Support sector investment in pharmacy immunisation to boost immunisation rates.

To address declining immunisation rates, New Zealand's health sector has introduced several initiatives to support vaccinators and improve public access. Te Whatu Ora recently implemented a process enabling pharmacists to expand their practice scope, increasing community access to paediatric immunisations. Investments have also been made in resources like Healthpoint which helps consumers find local vaccination services, and the Book My Vaccine platform which enhances the vaccination process. Expanding vaccination through reclassification is a vital strategy to boost immunisation rates in New Zealand. (MEDSAFE, 2019).

12 Labelling or draft labelling for the proposed new presentation(s) (if applicable)

N/A

13. Proposed warning statements (if applicable)

No changes are required to the current warning statement on packaging or data sheet.

14. Other products containing the same active ingredient(s) which would be affected by the proposed change

N/A

Part B- Clinical Context and Implications

1. Indications and dose

- *What is the medicine indicated for, and for which indication(s) is the reclassification application for?*

The approved indication for AREXVY is as follows:

> AREXVY *is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus RSV-A and RSV-B subtypes in:*
>
> - *adults 60 years of age and older.*
> - *adults 50 through 59 years of age who are at increased risk for RSV disease.*
>
> *Consideration should be given to official vaccine recommendations on the appropriate use.*

AREXVY is already classified for pharmacy-initiated administration for those 60 years of age and older. This application seeks to expand this to include those 50 to 59 at increased risk of RSV disease in line with the recently approved updated indication.

- *What is the evidence that the proposed indication is an OTC indication i.e., that the diagnosis and treatment can be understood by the consumer; that the risks of inappropriate treatment can be minimised?*

N/A

- *What is the treatment population for the indication (age, gender etc.)?*

Persons 50 to 59 years of age at increased risk of RSV disease and persons 60 years of age and older.

- *What is the dose and dose frequency of the medicine for this indication?*

AREXVY is administered as a single dose of 0.5 mL. The need for revaccination has not been established.

2. Presentation

- *What is the proposed dose form and strength of the medicine to be reclassified? Is this the same for all indications?*

AREXVY is available in a pack size of 1 vial of powder plus 1 vial of suspension.

- Powder for 1 dose in a vial (type I glass) with stopper (butyl rubber).
- Suspension for 1 dose in a vial (type I glass) with a stopper (butyl rubber).

Not all pack sizes and container types may be distributed in New Zealand

What disposal considerations need to be made for the medicine?

Disposal would be the same as for other vaccines. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Pharmacies providing a vaccination service are familiar with this practice and have the appropriate processes and equipment for dealing with the safe disposal of vaccines.

How practical and easy to use is the proposed presentation?

AREXVY is manufactured in a liquid adjuvant vial and powder vial presentation requiring reconstitution before use. Pharmacist vaccinators already reconstitute and administer AREXVY demonstrating understanding and ease of use with this process. Resources relating to reconstitution and administration are available via the Immunisation Advisory Centre website in addition to GSK resources.

3. Consumer benefits

- *What is the history of this medicine's use for the proposed indication(s) i.e., number of users; number of countries used in?*

AREXVY has received approval in 61 countries, including Europe, Japan, and the US, for preventing LRTD caused by RSV in individuals aged 60 and older. Additionally, it is approved in the US, EU, Japan, Australia, and New Zealand for use in people aged 50 to 59 at increased risk of RSV (GSK, 2025). To date 11 million doses up to March 2025 have been administered in the US alone to help protect millions of adults against RSV associated lower respiratory disease. (Gerber, 2025).

The efficacy and effectiveness of the AREXVY vaccine has already been well established through multiple studies and evaluations and has found to be efficacious in protecting those at risk of RSV disease as well as being well tolerated with a safety

profile comparable to other vaccines administered to older adults. (Ferguson, et al., 2024) (Papi, et al., 2023) (Ison, et al., 2024) (Bajema, et al., 2025)

- *To what extent is this medicine used for the proposed indication(s) i.e., duration of use, frequency of use?*

AREXVY is administered as a single dose. The need for revaccination has not been established.

- *What is the evidence that improved access is beneficial for the individual? What is the evidence of improved consumer involvement in their health? What are the benefits from a consumer viewpoint?*

Accessibility is crucial for vaccine uptake and equity. In New Zealand, several adult vaccines such as influenza, Tdap, COVID-19, and shingles are available through community pharmacies. IMAC recommends that AREXVY can be administered with several other vaccines, including those on the National Immunisation Schedule (IMAC, 2025) therefore ensuring access through the same channels is important for uptake.

The number of influenza vaccines and COVID-19 vaccines offered through pharmacy is significant, and the requirement of people to visit both a GP and a pharmacy for their vaccination would create additional barriers to access and increase the work burden on general practice. Enabling pharmacist vaccination is also important for outreach services, including vaccination in aged care facilities (Poudel, et al., 2019).

Accessing vaccinations through pharmacies offers numerous benefits for consumers, including greater convenience, as pharmacies often have longer hours and more locations compared to traditional healthcare settings, making it easier to get vaccinated without scheduling conflicts. This increased accessibility, along with shorter wait times, can lead to higher vaccination rates, which is crucial for those patients 50-59 at increased risk for RSV disease.

Pharmacies also provide comprehensive care, including medication counselling and health screenings, which supports holistic patient care. They are well placed to identify those at increased risk populations and offer timely and prompt vaccinations.

Additionally, vaccinations at pharmacies can be more cost-effective, reducing financial burdens for both consumers and healthcare systems. Pharmacists, as trusted healthcare professionals, play a vital role in educating and reassuring

patients about vaccine safety. Studies have shown that the convenience and accessibility of pharmacies significantly improve vaccine uptake and overall public health outcomes (Poudel et al., 2025).

4. Contraindications and precautions

- *What are the contraindications for the medicine and how easy are they to identify and prevent? What are the precautions for this medicine and how easy are these to understand?*

AREXVY is contraindicated to anyone with hypersensitivity to the active substances or to any component of the vaccine.

Before immunisation, vaccinators undergo training to screen patients for vaccination suitability. This process includes:

- Evaluating eligibility and suitability for vaccination, considering factors such as a history of underlying medical conditions, previous vaccinations, medical history, reactions to past vaccinations, Immunisation Handbook recommendations, and funding criteria.
- Pharmacist vaccinators have access to the Aotearoa Immunisation Register (AIR) to review and update a patient's vaccination history. They also use pre-vaccination screening checklists and consent forms during patient consultations and assessments.

- *Does the medicine have a low therapeutic index?*

N/A

- *What class effects need to be considered and what are the risks?*

As with all injectable vaccines key considerations are to:

- Ensure appropriate medical treatment and supervision are readily available to manage anaphylactic events following vaccine administration.
- Postpone vaccination for individuals experiencing an acute severe febrile illness; minor infections, such as a cold, should not delay vaccination.
- Recognise that not all vaccine recipients will elicit a protective immune response.
- Implement procedures to manage syncope (fainting) which may occur as a psychogenic response to needle injections, to prevent injury.

- Pharmacies providing vaccination services must comply with all requirements, including having emergency equipment and procedures in place.
- Vaccinators and other staff members must regularly undergo CPR and first aid training. Vaccinators are not permitted to work alone.

- *What are the risks of the medicine being used in an OTC environment?*

N/A

- *What other drug interactions need to be considered?*

As per the NZ data sheet AREXVY can be co-administered with high dose and adjuvanted seasonal influenza vaccines in addition to inactivated standard dose influenza vaccines. If AREXVY is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites (MEDSAFE, 2025).

- *What food and/ or drink interactions need to be considered?*

N/A

- *Are there any other restrictions when taking the medicine i.e., driving restrictions or operating machinery?*

No studies on the effects of AREXVY on the ability to drive and use machines have been performed.

- *Are there any special populations where exposure to the medicine needs to be restricted?*

People who are pregnant or attempting to get pregnant

- There are no data from the use of AREXVY in pregnant women. AREXVY is not recommended during pregnancy.

Breast-feeding

- There are no data on the excretion of AREXVY in humans or animals.

AREXVY is not recommended in breast-feeding or lactating women.

Fertility

- There are no data on the effects of AREXVY on human fertility. Effects on male or female fertility have not been evaluated in animal studies.

5. Undesirable effects

- *What are the known undesirable effects and the frequencies of these? Do these vary for special populations?*

Summary of the safety profile:

The safety profile presented below is based on a placebo-controlled Phase III clinical study (conducted in Europe, North America, Asia, and Southern hemisphere) in adults ≥ 60 years of age in which 12,467 adults received one dose of Arexvy and 12,499 received placebo. Variability of adverse events in special populations has not been evaluated.

- Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency:

System Organ Class	Frequency	Adverse reactions
Blood and lymphatic system disorders	Uncommon	lymphadenopathy
Immune system disorders	Uncommon	hypersensitivity reactions (such as rash)
Nervous system disorders	Very common	headache
Respiratory, thoracic, and mediastinal disorders	Common	rhinorrhoea
Gastrointestinal disorders	Uncommon	nausea, abdominal pain
Musculoskeletal and connective tissue disorders	Very common	myalgia, arthralgia
General disorders and administration site conditions	Very common	injection site pain, fatigue
	Common	injection site erythema, injection site swelling, fever, chills
	Uncommon	injection site pruritus
		pain, malaise

Frequency Definition: Very common ≥1/10; Common ≥1/100 to <1/10;
Uncommon ≥1/1,000 to <1/100; Rare ≥1/10,000 to <1/1,000; Very rare <1/10,000

- *What are the risks and consequences of known undesirable effects?*

Risks of adverse drug reactions are detailed above and in the proposed data sheet.

- *Are there any significant safety concerns for the medicine under review?*

Risks of adverse drug reactions are detailed above and in the approved data sheet. GSK continues to collect and analyse post marketing surveillance data as part of its ongoing pharmacovigilance obligations.

- *Have there ever been any withdrawals of the medicine or other regulatory actions taken for safety reasons (during a time period or in a specific jurisdiction)?*

No

- *Are there any withdrawal effects following cessation of use of the medicine?*

No

6. Overdose

- *Is there a potential for overdose of the medicine?*

There is low potential for overdose as the vaccine will be administered by healthcare practioners who have access to vaccination records to ensure appropriate scheduling of vaccine for patients.

- *What are the consequences of overdose of the medicine?*

N/A

- *Are there any reports of overdose of the medicine?*

There are no current reports of overdose from the global database.

7. Medication errors and abuse/ misuse potential

- *Would reclassification affect the risk of unnecessary use?*

This is unlikely, a vaccination is usually a memorable event, and the use of a National Immunisation Register will provide the vaccinator with an up-to-date vaccination history to minimise the risk of a double dose.

- *Should the medicine be provided with necessary tools to allow correct dosing e.g., liquids supplied with a measuring device?*

Two vials are provided for powder and suspension. A syringe and needles are required to reconstitute the powder and administer the vaccine (not provided).

- *What are the reported medication errors post-market?*

Administration errors are recorded when reported to IMAC, GSK and or CARM in New Zealand. However, the Applicant does not expect there to be changes in the type of errors reported because of expanding the indication to include 50 to 59 at increased risk.

- *What are the reported cases of abuse/misuse/accidental overdose?*

N/A

- *How would reclassification affect import considerations?*

The vaccine still holds the prescription-only classification until point of administration. As such, there are no changes in requirements around import or distribution.

- *What is the addiction potential of the medicine?*

N/A

8. Communal harm and/or benefit

- *What are the possibilities of community harm resulting from wider use of the medicine in question (e.g., the development of antibiotic resistance in bacteria or increased immunisation rates)?*

The Applicant does not expect an increase in community harm resulting from this reclassification. Like other vaccines offered in pharmacies, there is a risk of inappropriate administration or double dosing due to the increased number of providers. However, this risk can be reduced by carefully reviewing immunisation records (AIR). Additionally, patients at risk might not get timely access to the vaccine or may remain unprotected against RSV, which is a major concern.

- *What are the possibilities of community benefit resulting from wider use of the medicine in question (e.g., greater herd immunity as a result of improved access to a communicable disease vaccine)?*

Allowing access AREXVY through community pharmacies for people aged 50 to 59 at increased risk of RSV disease is expected to significantly increase vaccination uptake in this age group, ensuring that individuals with the highest need receive protection. Additionally, distributing vaccination services across various providers will help reduce the burden on general practice.

9. Integrated benefit-risk statement

A summary of the reclassification benefits

- Pharmacists in New Zealand are crucial in improving community access to immunisations. Allowing people aged 50 to 59 at increased risk of RSV disease

to access AREXVY through pharmacies will enable them to receive the vaccine from a wider range of vaccinators. This will also help distribute the workload more evenly among authorised and pharmacist vaccinators, reducing pressure on primary care sectors.

- Pharmacists have been administering influenza vaccines since 2013, and the COVID-19 pandemic has shown that community pharmacies are trusted vaccination providers for New Zealanders. Since AREXVY can be co-administered with other adult vaccines, having both available from the same provider is essential for increasing vaccine uptake.
- In addition to influenza vaccines, pharmacists have expanded their services to include other essential immunisations. Since August 2022, authorised pharmacists have been permitted to administer the diphtheria, tetanus, and pertussis vaccine (BOOSTRIX). By May 2024, over 40% of pharmacies had administered at least one of the vaccines added to the Pharmaceutical Schedule, such as human papillomavirus (HPV), meningococcal, and shingles vaccines (Atashi, 2024).
- Traditionally, authorised vaccinators have been the main providers of scheduled and funded vaccines. Reclassifying AREXVY will allow more consumers to receive it from authorised vaccinators without needing a prescription.

A summary of the reclassification risk of harm

It is important to ensure widened access for at risk patients to AREXVY to ensure protection against RSV disease. The potential harm from the proposed reclassification is minimal. Similar to other vaccines provided in pharmacies, there may be an increased risk of inappropriate administration or double dosing due to the larger number of providers offering vaccination services. However, this risk is mitigated through the correct review of immunisation records (AIR). It is also important to consider that patients at risk may not have timely access to the vaccine or may remain unprotected against RSV disease, which is a significant concern

A summary of the need for the medicine at the classification proposed

- Community pharmacies have established themselves as a widely accepted and frequently utilised provider for vaccinations, ensuring equitable and accessible

uptake. Reclassification will enable consumers in this population to receive unscheduled or unfunded vaccinations from authorised vaccinators without needing a prescription.

- Making AREXVY available through pharmacies for people 50 to 59 AIR is essential to prevent the need for individuals in this population to visit both a pharmacy and a GP. If AREXVY is only available through general practice, there is a risk that influenza and COVID-19 vaccinations would also shift to general practice, further increasing the burden on already busy general practice settings.

Precedent – how are other medicines in the same class classified?

AREXVY is the only older adult RSV vaccine available in New Zealand. Many other adult vaccines are administered through community pharmacy by pharmacist vaccinators. Current vaccines available through pharmacy without a prescription: (IMAC, 2024)

- Influenza from 3 years
- Diphtheria, tetanus, and pertussis from 13 years of age and older (maternal) and from 18 years of age and older (non-maternal)
- COVID-19 from 3 years
- HPV9
- MMR from 3 years
- Meningococcal B from 16 years
- Meningococcal ACYW from 16 years
- Varicella zoster for adults 50 years and older, or 18 year and older at increased risk of herpes zoster
- Cholera (as a pharmacist only medicine)

10. Risk mitigating strategies

- *Are there any risk mitigation strategies required? If so, what risk mitigation strategies are required e.g., healthcare professional education; integration of care; consumer information to be provided etc?*

Potential Risks	***Mitigation Plan***
Identification of eligible patients 50-59 YOA at increased risk of RSV disease	**<u>Training and Education</u>** Pharmacists are trained to identify and confirm through patient history, clinical records, dispensing data, and/or communication with physicians whether a

	person should be vaccinated with AREXVY. Pharmacists are required to maintain their competency in understanding who should receive any vaccine, as well as their administration. This is done through both self-learning and regular updates as part of their scope of practice as vaccinators. **Health New Zealand Immunisation Handbook** Updates to the clinical guidelines in the immunisation handbook will help guide vaccinators to identifying eligible cohorts for vaccination in the 50-59 at increased risks groups. **Education campaigns** Pharmacies benefit from the support of regional immunisation coordinators and professional development programs offered by organisations such as IMAC. Through these initiatives, pharmacists receive regular updates and education about the latest criteria and eligibility. This ongoing education reinforces their ability to vaccinate these individuals safely and effectively without requiring a prescription. **Education materials and resources** In addition to the current resources available for pharmacists on identifying eligible patients aged 60 years and older who will benefit from AREXVY vaccination, GSK will be providing the relevant educational materials and resources to pharmacist to help them identify patients who are 50-59 at increased risk of RSV and

	who benefit from vaccination.
Healthcare professionals are not familiar with the reconstitution and administration of AREXVY	**Availability of the Data sheet and package insert** The data sheet describes reconstitution steps. Reconstitution of AREXVY is similar to the preparation of several other common vaccines. All necessary information on reconstitution, administration and precautions will be available for reference and use for all prescribers and administrators. **Provision of Educational resources and materials** In addition, GSK will undertake to provide relevant educational materials and resources to healthcare providers on how to correctly reconstitute and administer AREXVY.
Adverse events or injection site reaction management	**Data sheet** AREXVY's data sheet sets out the requirements for the management of adverse events, including the website for reporting adverse events. **Education materials and resources** GSK will be providing the relevant educational materials and resources for AREXVY to help healthcare providers as well as consumers understand how to manage adverse events and report them.
Unnecessary vaccinations	The AIR is a national register for vaccines and is a centralised platform to view individuals' vaccination status. The use of this register mitigates the risk of inadvertently administering an additional dose of the same vaccine when not scheduled. With the introduction of the AIR, pharmacist vaccinators are required to have access and establish an individual's

	vaccination history.

- *What is the evidence that these proposed risk mitigation strategies would be effective?*

Continuous training and education for pharmacists, along with updates to immunisation guidelines, ensure they can identify eligible patients aged 50 to 59 at increased risk of RSV. Detailed reconstitution steps and educational resources boost healthcare professionals' confidence in administering AREXVY. Clear guidelines for managing adverse events and additional educational materials ensure proper response and reporting. Using centralised vaccination registers like the AIR reduces the risk of unnecessary vaccinations by providing real-time access to vaccination histories. Overall, these strategies improve the accuracy, safety, and effectiveness of AREXVY administration.

- *What post-market surveillance activities would be carried out?*

Post marketing surveillance activities would not change as a result of this proposal.

- *Is the proposed reclassification supported by professional bodies?*

Yes. Evidence of support by the Pharmacy Guild New Zealand, Green Cross Health and Unichem Pakuranga Pharmacy are provided in the attached letters.

Conclusion

A brief summary of the purpose of the submission and any concluding remarks

AREXVY is an effective vaccine for at-risk adults, demonstrating a well-established safety profile. The immunological response in individuals aged 50 to 59 is comparable to those aged 60 and above, confirming its efficacy and safety across these age groups (Ferguson, et al., 2024). Ongoing post marketing surveillance commitments continue here in New Zealand and globally to continue to monitor the use of AREXVY in at risk individuals. Providing access to AREXVY for individuals aged 50 to 59 years at increased risk of RSV through pharmacies is crucial to ensuring timely and equitable access to vaccination, alleviating the burden on general practice and leverages the trust and convenience associated with community pharmacies. By enabling pharmacists to administer AREXVY to this age group at increased risk of

RSV disease, we can enhance vaccination uptake, protect vulnerable populations, and improve public health outcomes.

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20th May 2025

Alia Mahgoub
GlaxoSmithKline New Zealand
Level 12, AON Centre, 29 Custom Street West,
Auckland 1010

Sent via email to: alia.a.mahgoub@gsk.com

RE: Letter of Support – Proposed Reclassification of Arexvy for Adults Aged 50–59 Years at Increased Risk of RSV Disease

Kia Ora Alia,

On behalf of Green Cross Health, I am writing to express our strong support for GlaxoSmithKline (GSK) New Zealand's proposal to the Medicines Classification Committee to reclassify the Arexvy vaccine, enabling pharmacist administration for adults aged 50 to 59 years who are at increased risk of respiratory syncytial virus (RSV) disease.

Recent New Zealand data shows that individuals in the 50–59-year age group with chronic respiratory conditions such as COPD and asthma face hospitalisation rates up to ten times higher due to RSV compared to those without such conditions. These risks are disproportionately borne by Māori and Pacific communities, who also experience longstanding inequities in access to healthcare services.

Allowing pharmacists to administer Arexvy to this cohort will help bridge significant access gaps. Community pharmacies are often the most accessible healthcare providers, offering extended hours and walk-in services without requiring GP enrolment, critical when many general practices are closed to new patients. This model promotes equity by enabling timely access to preventive care for those who may otherwise go without.

GSK's proposed reclassification aligns with recent international regulatory approvals by the US FDA, European Medicines Agency, and Australia's TGA, which have extended Arexvy's indication to include adults aged 50–59 years at increased risk of RSV. This international precedent supports the clinical rationale for pharmacist supply in New Zealand.

Locally, the pharmacy-based rollout of Arexvy for adults aged 60 and over has already demonstrated safe and effective implementation, with 154 doses administered successfully in Q1 2025. Pharmacists are well-positioned to extend this delivery model to the 50–59-year-old at-risk cohort.

Current guidance from the Immunisation Advisory Centre (IMAC) and Medsafe supports co-administration of RSV vaccines with influenza and COVID-19 vaccines. Pharmacist vaccinators are well-equipped to integrate Arexvy into this co-administration strategy during the winter respiratory season.

Reclassification aligns with Te Whatu Ora's broader strategy to expand pharmacy's immunisation role and improve access. Existing investments in digital booking platforms,

vaccinator training (including paediatric vaccines), and community pharmacy immunisation capacity demonstrate strong system readiness.

Pharmacist vaccinators are trained, accredited, and experienced in managing risk and maintaining high standards of safety. Extending their role to include Arexvy for this additional risk group is a clinically appropriate and efficient use of existing workforce capacity.

GSK's proposal supports an equitable, scalable, and timely response to the growing burden of RSV in middle-aged adults with chronic conditions. Green Cross Health strongly endorses your submission to the Medicines Classification Committee and believe this change will lead to better health outcomes, reduced strain on general practice, and greater immunisation coverage for some of Aotearoa's most vulnerable.

Ngā mihi nui,

Joel Sathuluri
National Operations Commercial Pharmacist

PHARMACY GUILD OF NEW ZEALAND

15 May 2025

Alia Mahgoub
Senior Medical Affairs Manager
GlaxoSmithKline

Sent via email to: alia.a.mahgoub@gsk.com

Re: Support for the reclassification of AREXVY vaccine for adults aged 50–59 years who are at increased risk of RSV disease

The Pharmacy Guild of New Zealand (Inc.) (the Guild) is a national membership organisation and the largest representative body for community pharmacy owners. We provide leadership on sector-wide issues and advocate for the professional and commercial interests of community pharmacy.

On behalf of New Zealand's community pharmacists, the Guild strongly supports GlaxoSmithKline's (GSK) proposal to reclassify the Respiratory Syncytial Virus (RSV) vaccine, AREXVY, that would enable pharmacist vaccinators and other authorised vaccinators to administer the vaccine to adults aged 50–59 years who are at increased risk of RSV disease.

Respiratory syncytial virus (RSV) can cause serious respiratory illness, particularly in older adults with underlying medical conditions. International developments highlight the value of vaccination with the RSV vaccine for younger at-risk adults. In June 2024, the United States FDA approved AREXVY for use in adults aged 50–59 at increased risk, followed by similar approval from the European Commission in August 2024. AREXVY is already approved for older adults in several major jurisdictions, including the United Kingdom, European Union, United States, Canada, and Japan, reflecting widespread confidence in its safety and efficacy.

Clinical evidence supports expanding access to AREXVY for adults aged 50–59 who are at with increased risk of RSV disease. A global Phase III trial demonstrated that immune responses in this cohort were non-inferior to those observed in older adults, while AREXVY's efficacy in adults aged 60 and above exceeded 82% in preventing RSV-related lower respiratory tract disease. This strong evidence has led regulators and advisory bodies internationally to recommend vaccinating at-risk individuals in the 50-59 age group ahead of the RSV season.

Importantly, AREXVY can be co-administered with inactivated seasonal influenza vaccines, including high-dose and adjuvanted formulations, as per the New Zealand data sheet. While clinical studies observed numerically lower RSV A and B neutralising titres and influenza haemagglutination inhibition titres when administered concurrently—compared to separate administration—this finding was not consistent across studies and its clinical relevance remains unclear. Importantly, the **safety profile** of AREXVY when co-administered with influenza vaccines was **comparable** to administration alone. This compatibility supports the practical integration of RSV vaccination into existing winter immunisation campaigns, improving access and convenience for patients and reducing demands on other parts of the health system.

New Zealand pharmacists have rapidly incorporated RSV vaccination into routine practice alongside influenza, Covid-19 boosters, and other immunisations. Since AREXVY was approved for use in adults aged 60 and over, community pharmacies have administered 154 doses between

Your community pharmacist:
the health professional you see most often.

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January and April 2025. Pharmacist vaccinators are trained to conduct comprehensive assessments and consultations before and after vaccination events, offer tailored education, and address concerns to support patients and caregivers in making informed choices. With robust digital infrastructure and access to the national Aotearoa Immunisation Register (AIR), pharmacists are well-equipped to support wider access to RSV vaccination and would enable patients to receive RSV protection at the same convenient locations where they already receive other vaccinations, particularly during the peak flu season. Community pharmacy-based immunisation programmes have consistently demonstrated their effectiveness in increasing vaccine uptake, and a similar approach for RSV immunisation will help reach those with the highest need. According to GSK's modelling, vaccinating this group could prevent more than 18,500 GP visits and nearly 4,000 hospitalisations across New Zealand over a three-year period.

Equity considerations are also critical. Māori and Pacific peoples experience disproportionately high rates of severe RSV disease and hospitalisation and are more likely to live with chronic conditions such as COPD, asthma, and heart disease, further increasing their risk. These populations also face greater barriers to accessing primary healthcare services. Expanding pharmacist vaccinator access, among others, to administer AREXVY to at-risk adults aged 50–59 would improve timely access to vaccination for underserved populations and rural areas where access to primary healthcare providers may be limited or overloaded. By reducing the need for general practice visits solely for vaccination purposes of those high-risk patients, healthcare resources can be reallocated more efficiently, and patients benefit from increased convenience and accessibility, allowing them to choose where and when they feel comfortable and is convenient to receive their vaccinations. When combined with targeted community outreach and culturally appropriate health messaging, community pharmacy-based delivery provides a practical and effective strategy to address reduce persistent immunisation inequities and improve health outcomes for priority populations.

Finally, the proposed reclassification is well aligned with national immunisation strategies. Pharmacists play a vital role in Health New Zealand's winter readiness and equity campaigns, serving as key partners in delivering accessible vaccination services. Existing tools such as Book My Vaccine, integrated with AIR, already support the coordination of community pharmacy-based vaccinations. Expanding access to AREXVY will enable at-risk individuals to receive RSV protection during routine visits for influenza or other immunisations. This approach is consistent with current guidance from the Immunisation Advisory Centre (IMAC) and precedents set by other recent vaccine reclassifications.

For these reasons, the Guild formally supports GSK's request that the Medicines Classification Committee approve the reclassification of AREXVY to allow administration to adults aged 50–59 years who are at increased risk of RSV disease. This change will expand timely protection to a vulnerable population, align New Zealand with international best practice, and make greater use of community pharmacy capacity to improve public health outcomes.

If you have any questions about our comments, please contact our Senior Advisory Pharmacists, Martin Lowis (martin@pgnz.org.nz, 04 802 8218) or Cathy Martin (cathy@pgnz.org.nz, 04 802 8214).

Yours sincerely,

Nicole Rickman
General Manager – Membership and Professional Services

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21 May 2025

Medicines Classification Committee
Secretary
Medsafe Wellington

Subject: Support for Reclassification of Arexvy for Use in Adults Aged 50–59 Years

I am writing to express support for the proposed reclassification of the respiratory syncytial virus (RSV) vaccine, **Arexvy**, to include adults aged **50 to 59 years**, particularly in light of mounting evidence demonstrating the burden of RSV in this age group—especially among individuals with chronic health conditions and those from high-risk populations in Aotearoa New Zealand.

Recent local data highlights a pressing need to broaden access to preventative measures such as RSV vaccination. Notably, Prasad et al. (2020) report that RSV hospitalisation rates are 10 times higher in adults aged 50–64 with chronic obstructive pulmonary disease (COPD) and 7–8 times higher in those with asthma, compared with individuals without these conditions. These findings indicate a substantial disease burden in people under 65 with underlying medical conditions.

Furthermore, Turner et al. (2024) report continued elevated rates of RSV-related hospitalisations post-COVID, especially among young infants, the elderly, Māori and Pacific peoples, and those residing in deprived communities. This study reinforces the ongoing vulnerability of certain populations and the persistence of health inequities that demand targeted public health action.

Given that Māori and Pacific populations are significantly more likely to have chronic medical conditions ($P < .001$), failure to expand RSV vaccine access could exacerbate existing disparities. Improved access through pharmacy-based vaccination services—enabled by reclassification—could help mitigate these inequities by reaching underserved groups with greater flexibility and lower barriers.

Expanding Arexvy's indication to those aged 50–59 with or without chronic conditions is a logical, evidence-based public health intervention. It aligns with goals to reduce hospitalisation rates, alleviate pressure on the healthcare system, and promote equity of access in preventive healthcare.

Community pharmacists are uniquely positioned to play a central role in delivering these vaccinations, particularly to hard-to-reach populations. With their accessibility, extended hours, and trusted relationships within local communities, pharmacists will continue to be critical partners in improving immunisation coverage and addressing persistent health inequities across Aotearoa.

As the clinical site lead of Unichem Pakuranga Pharmacy, I respectfully urge the Medicines Classification Committee to strongly consider and approve this reclassification proposal considering the strong epidemiological rationale and the opportunity to better protect vulnerable populations across New Zealand.

Sincerely,

Vicky Chan
Clinical Site Lead
Unichem Pakuranga Pharmacy